Anti-COVID-19 Monoclonal Antibody (MAb) Order Packet

Treatment for COVID-19 Case

Ordering process:

1. Complete Patient Demographics information below.
2. Confirm patient's eligibility on page one of order set.
3. Review with patient the potential risks and benefits of MAb treatment as outlined in the consent form. Affirm the patient's desire to proceed. Provider signs the consent form, and has another person sign as witness to patient's verbal consent.
4. Fax the following materials to 724-543-8855. Any discrepancies will be reviewed by physician leadership.
    a. Order Packet (including Patient Demographics, Eligibility Form, and Order Set)
    b. Copy of positive COVID-19 test (antigen or RT-PCR)
    c. Signed COVID-19 MAb therapy consent form
    d. List of current medications.
    e. H&P or most recent clinic note.
5. Physician office will contact ACMH Scheduler to make appointment for infusion.
6. At appointment, patient will receive required materials on drug.
7. If patient is hypoxic at arrival to appointment, MAb will NOT be administered.
8. Patient will be infused with MAb over one hour, and he/she must stay for an hour of observation after infusion complete.

Patient Demographics

Patient Name: _____ Date of Birth: _____

Social Security Number: _____

Patient Phone Number: _____

Date of onset of COVID-19 symptoms: _____ (must be within 10 days of infusion)

Date of positive COVID-19 test: _____

Ordering Physician Name: _____ (Must be MD or DO - no APP orders permitted)

Physician Phone Number: _____

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Org. 10/21

ACMH | Hospital

Patient Label

CONSENT TO ADMINISTRATION OF ANTI-COVID-19 MAb

I, _____ consent to the administration of monoclonal antibody (MAb) therapy for coronavirus disease 2019 (COVID-19), with casirivimab/imdevimab or bamlanivumab/etesevimab. These have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) for the treatment of mild to moderate COVID-19 in people at high risk of progressing to severe disease and/or hospitalization. No treatment will be administered if hypoxia (low oxygen levels) are present at the time of therapy appointment. The drug is administered intravenously by placing a small needle or catheter into a vein and slowly injecting the solution over an hour. You may or may not experience the listed side effects associated with these treatments. There may also be unforeseen complications, injury, or even death from unknown causes associated with this administration. Risks/complications involved: hypersensitivity including allergic reactions and infusion related reactions - fever, chills, nausea/vomiting, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness. Likelihood of success: I understand that there have been no guarantees made to me that this medication would improve my condition (This area is specific to the patient) _____

_____

Your signature below constitutes your acknowledgment: (1) that you have read and agreed to the foregoing, (2) that the associated risks and possible side effects have been explained to you and that you have all the information that you desire, (3) you have been provided the "Fact Sheet for Patients, Parents and Caregivers" prior to receiving therapy, (4) agree to remain for an hour of observation after infusion is completed, and (5) agree to not receive any vaccine against SARSCoV-2 for at least 90 days after monoclonal antibody therapy. I have been given ample time to ask questions regarding this administration, risks and alternatives with my physician and they have been answered.

Patient: _____ _____/_____
(Or person authorized to consent for patient) Date Time

_____ _____ _____/_____
Relationship to Patient Witness Date Time

If verbal/telephone consent,

2nd witness is required: _____ _____/_____
2 nd witness Date Time

I have explained to the patient, parent (guardian or representative) the nature of the above procedure or treatment as well as the reasonably anticipated risks, complications and alternatives to such treatment. The foregoing consent was read, discussed, and signed in my presence, and, in my opinion, the person(s) so signing did so freely with full knowledge and understanding.

_____ _____/_____
Physician Signature Date Time

ACMH
HOSPITAL

One Nolte Drive
Kittanning, PA 16201

COVID 19 Outpatient Monoclonal Therapy Order Set
Infusion Clinic

Authorization is given to the pharmacy to dispense and to the nurse to administer the generic or chemical equivalent unless otherwise ordered.

DATE	TIME	
		Orders for Monoclonal Antibodies should be faxed to 724-543-8855
		Requirements: Symptoms of COVID 19 for less than 10 days; Positive COVID-19 test (antigen of PCR)
		12 years of age or older, does not require oxygen therapy due to COVID-19 or an increase in baseline oxygen
		flow rate due to COVID-19 on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity
		and high risk for progression of severe COVID-19
		☐ **YES** ☐ **NO**
		Date of Symptom Onset: _____ **Date of Positive Test Result:** _____
		***If yes, then patient must meet the following criteria to receive Monoclonal Antibody Infusion*
		Must meet at least one of the following criteria (check all that apply)
		☐ Greater than or equal to 65 years of age
		☐ BMI ≥ 25 kg/m2 Weight: >40kg Height:
		☐ Pregnant
		☐ Chronic Kidney Disease
		☐ Diabetes Mellitus
		☐ Immunocompromised (by medical condition or treatment)
		Describe:
		☐ Cardiovascular Disease (including congenital heart disease)
		☐ Hypertension
		☐ Sickle Cell Disease
		☐ Neurodevelopmental Disorder
		☐ Medical-dependent technology dependence (i.e. tracheostomy, gastrostomy, etc)
		☐ Other factors (including race and ethnicity) that increase risk of severe illness
		☐ Chronic Lung Disease (COPD, asthma, pulmonary hypertension, cystic fibrosis)
		Medical Record Documentation
		• The fact sheet was given to patient and/or caregivers
		• Informed of Alternatives to Monoclonal Antibody treatment
		• Informed that the Monoclonal Antibody treatment is a unapproved drug and is Authorized for Emergency Use by the FDA
		• Patient Agrees to Treatment
		VORB/TORB: _____ Date: _____ Time: _____
		Physician Signature: _____ Date: _____ Time: _____

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Kittanning, PA 16201

COVID 19 Outpatient Monoclonal Therapy Order Set
Infusion Clinic

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DATE	TIME	COVID-19 MONOCLONAL THERAPY
		Please check box:
		☐ Monoclonal Antibody Therapy (drug to be chosen by ACMH Pharmacy based on stock and availability)
		DIRECTION FOR ADMINISTRATION:
		Casirivimab/imdevimab (Regen-COV)
		• Attach infusion set containing 0.2 micron filter to IV bag
		• 600mg casirivimab with 600mg imdevimab in 0.9% sodium chloride IV Infusion x1
		• Infuse over 41 minutes. Total volume to be infused = 110 mL
		• Observe for hypersensitivity within the first 5 minutes and then 1- hour post infusion
		• Set should be flushed to ensure delivery of the required dose with 0.9% Sodium Chloride
		• Flush INT PRN
		• Discontinue IV and discharge patient, 1 hour after infusion completed and pt without reaction
		Bamlanivumab/etesevimab
		• Attach infusion set containing 0.2 micron filter to IV bag
		• 700 mg bamlanivumab with 1400 mg etesevimab in 250mL 0.9% NaCl 0.9% IV Infusion over 1 hour
		• Infuse over 60 minutes. Total volume to be infused = 310 mL
		• Observe for Hypersensitivity within the first 5 minutes and then 1- hour post infusion
		• Set should be flushed to ensure delivery of the required dose with 0.9% Sodium Chloride
		• Flush INT PRN
		• Discontinue IV and discharge patient, 1 hour after infusion completed and pt without reaction
		REACTION MEDICATIONS (System COVID-19 Monoclonal Therapy)
		Please check box:
		☐ Reaction Medication (drugs given in event of a patient reaction)
		Mild / Moderate Reaction
		• Pause the infusion for fever, chills, nausea headache, rash including uritcaria, pruritus, myalgia, or dizziness and call provider for further instructions
		• Call 911, have the patient transported to the ACMH Emergency Department
		Severe/ Anaphylactic Reaction
		• Turn off infusion for angioedema, shortness of breath, hypotension, dyspnea, wheezing or or stridor, immediately call 911 (if necessary, begin CPR).
		• Administer O2 to maintain saturation above 94%
		• Administer EPINEPHrine (ADRENALIN) 0.3 mg IM every 5 mins PRN severe or anaphylactic reaction (up to 3 doses)
		• DiphenhydrAMINE (BENADRYL) 50 mg IV once PRN severe or anaphylactic reaction
		• As soon as EMS arrival, transport to ACMH Emergency Department
		VORB/TORB_____ Date: _____ Time: _____
		Physician Signature:_____ Date: _____ Time: _____

Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab for Coronavirus Disease 2019 (COVID-19)

You are being given two medicines together called **bamlanivimab and etesevimab** for the treatment or post-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab and etesevimab.

Receiving bamlanivimab and etesevimab may help to treat COVID-19 in certain people, or help to prevent COVID-19 in certain people who have been exposed to someone infected with SARS-CoV-2 or who are at high risk of an exposure because of where they live, such as nursing homes or prisons.

Read this Fact Sheet for information about bamlanivimab and etesevimab. Talk to your healthcare provider if you have questions. It is your choice to receive bamlanivimab and etesevimab or stop them at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What are bamlanivimab and etesevimab?
Bamlanivimab and etesevimab are investigational medicines used together in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for developing severe COVID-19, including hospitalization or death for:

- **treatment** of mild to moderate symptoms of COVID-19, OR

- **post-exposure prophylaxis for prevention** of COVID-19 in persons who are:
    - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**
    - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications), **and**
        - have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **or**

- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

Bamlanivimab and etesevimab are investigational because they are still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab and etesevimab to treatment or prevention of COVID-19. Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of bamlanivimab and etesevimab together for the treatment of COVID-19 and the post-exposure prophylaxis for prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section **"What is an Emergency Use Authorization (EUA)?"** at the end of this Fact Sheet.

What should I tell my healthcare provider before I receive bamlanivimab and etesevimab?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have received a COVID-19 vaccine
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive bamlanivimab and etesevimab?

- Bamlanivimab and etesevimab are given to you at the same time through a vein (intravenous or IV).
- You will receive one dose of bamlanivimab and etesevimab by IV infusion. The infusion will take 21 – 60 minutes or longer. Your healthcare provider will determine the duration of your infusion.

What are the important possible side effects of bamlanivimab and etesevimab?

Possible side effects of bamlanivimab and etesevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab and etesevimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness, and sweating. These reactions may be severe or life threatening.
- Worsening of COVID-19 symptoms after bamlanivimab and etesevimab therapy for active infection: You may experience new or worsening symptoms after infusion for mild to moderate COVID-19, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab and etesevimab. Not a lot of people have been given bamlanivimab and etesevimab. Serious and unexpected side effects may happen. Bamlanivimab and etesevimab are still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab and etesevimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab and etesevimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?
Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with bamlanivimab and etesevimab. Should you decide not to receive bamlanivimab and etesevimab or stop it at any time, it will not change your standard medical care.

What other prevention choices are there?
Vaccines to prevent COVID-19 are approved or available under Emergency Use Authorization. Use of bamlanivimab and etesevimab does not replace vaccination against COVID-19.

Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines for post-exposure prophylaxis for prevention of COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA for post-exposure prophylaxis for prevention of COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab and etesevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab and etesevimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with bamlanivimab and etesevimab?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?
- Ask your healthcare provider
- Visit www.LillyAntibody.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab and etesevimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Bamlanivimab and etesevimab have not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for bamlanivimab and etesevimab together is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Literature revised September 16, 2021

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